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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 16

Application Number: 09/051,827
Filing Date: May 01, 1998
Appellant(s): ZIMMERMANN ET AL.

Hesna J. Pfeiffer
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed 7/5/01.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

This appeal involves claims 2, 3, 14, 16, 18-19.

Claim 15 is allowed.

Claims 4, 6 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The discrepancy from the Appeal Brief arises from the fact that a new argument presented in the Appeal Brief on the description issue overcame that rejection, and therefore the art rejection was overcome as well.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: As set forth above, the description issue and the art rejection are dropped. In terms of the Final Rejection, note also a) the issue concerning the form of claim 2 can be handled by having the claim represented in clean form and b) the claim 16 issue will be handled by treating the problem as a typographical error.

(7) Grouping of Claims

The appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because whether or not the claims stand or fall together does not depend on the nature of the claims themselves, insofar as whether they are compound, process of method claims. Basically, only one of the two rejections (the description rejection) has multiple claims, and in the examiner's view, these stand or fall together because the issue equally affects them all.

(8) Claims Appealed

A substantially correct copy of appealed claim 16 appears on page 23 of the Appendix to the appellant's brief. The minor errors are as follows: The penultimate "1" does not actually appear in the claim. The examiner will fix this as a typographical error. This issue does not affect any rejection now present.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 2, 3, 14, 16, 18-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

New Matter Issue

One of the choices for R_4 is an aliphatic hydrocarbon radical, and on that radical there can be many substituents, including "thio", listed in last line of page 84. On amendment, this was changed to "mercapto", which is the current claim language. However, changing wording to correct an error requires that one skilled in the art "appreciate not only the existence of an error, but what the error is", *Ex Parte Brodbeck*, 199 USPA 230. In that case, affidavits were submitted to show that one skilled in the art would know what was actually intended. That has not been done here, and it is unclear what was originally intended. That is, while one skilled in the art would appreciate that an error exists, viz., using "thio" instead of the correct term, one does not know what the error is because it is not at all clear what the correct term would be.

The term "thio" is not a name for a substituent, or a class of substituents, but a generic term, a generic term, indicating only the presence of sulfur in some form. There could have been intended three possible choices:

1. Thioxo, doubly bonded sulfur (=S).

2. Mercapto (-SH).

3. It can also denote replacement of some other atom (normally, oxygen or carbon) by S, as in "thioalkoxy", where O in alkyl-O- is replaced by S to give alkyl-S-. Or perhaps some term which began with "thio", like "thiophene", was intended.

(11) Response to Argument

In trying to show that one skilled in the art would have known that "mercapto" was intended, Applicants first pointed to page 29, first full paragraph. This is unpersuasive for the following reasons:

A. This cannot be understood to define "thio" because the term "thio" never appears on the page.

B. The paragraph in fact is a presentation of examples of what is meant by "etherified mercapto group". Specifically, it sets forth what the etherifying group can be in the phrase "etherified mercapto group", i.e., it could be etherified with optionally substituted aryl. That is irrelevant to the issue at hand because the claim language does not have an etherified anything. Thus, it is directed to a question unrelated to the original or current claim language.

C. The context is entirely different. The paragraph is discussing a protected amino, viz. an amino protected with an "etherified mercapto group". The issue at hand is the definition of a substituent in the R_4 radical. These are unrelated.

In summary, the fact that the word "mercapto" does appear in the specification in an entirely unrelated circumstance, on a page where "thio" does not appear, does not lead one of ordinary skill in the art to believe that "thio" means mercapto.

In the Appeal Brief, appellants now point to page 8, line 13, where the variable R_7 and R_8 can be, among other, acyclic hydrocarbyl, substituted by, among others, "mercapto". The same issues A. and C. apply here as well.

Indeed, the examiner must point out that the use of "mercapto" in different contexts can just as well be used as an argument that "mercapto" was <u>not</u> intended

when "thio" was written. The use of the term "mercapto" in the specification indicates that applicants were aware of this term. The fact that elsewhere, the different term "thio" was used could be evidence that a different meaning was intended. Although this is not a strong inference, this argument is no weaker than the argument that appellants have presented.

The Indefiniteness Issue

Claim 19 recites " ... tumors which are responsive to the inhibition of $p34^{cdc2}$/cyclin B^{cdc13} kinase." However, this is not, in any way, a defined, or generally understood, set of tumors. One cannot go into a book or other prior art source and find a generally accepted list of such tumors, the way one can with "hormone dependent tumors". It is not a term with an art-recognized meaning, or indeed, a conventional term at all, nor have applicants asserted that one of ordinary skill in the art knows which tumors this refers to. The specification contains no list of tumors which are included, or a list of tumors which are not. Thus, one of ordinary skill in the art is forced to unduly experiment to determine its scope.

Put differently, problem is that the claim is drawn to the treatment of an unknown set of tumors. Determining whether a given type of cancer (e.g. pancreatic cancer) falls into the category of those "responsive to the inhibition of $p34^{cdc2}$/cyclin B^{cdc13} kinase" is a difficult, lengthy, and painstaking task. It represents basic research, and is not routine at all.

Suppose that a given $p34^{cdc2}$/cyclin B^{cdc13} kinase inhibitor X when administered to a patient with Tumor D (e.g. pancreatic cancer) does not obtain a response. Does one

then conclude that Tumor D, pancreatic cancer, does not fall within claim 19? Keep in mind that:

A. It may be that the next patient will respond. It is completely normal for anti-cancer pharmaceuticals to work only with some people, not all. Thus, how many need to be tested?

B. It may be that the wrong dosage or dosage regimen was employed. It is quite common for pharmaceuticals to work at one dosage, but not at another which is significantly higher or lower. Furthermore, the dosage regimen may be vital --- should the drug be given e.g. once a day, or four times in divided dosages? Thus, how many dosages and dosage regimens must be tried before one is certain that this pharmaceutical won't affect Tumor D?

C. It may be that the particular compound X picked simply isn't potent enough for Tumor D, but that another inhibitor Y is potent enough, so that D really does fall within the claim. That is, even if all attempts to get Tumor D to respond to compound X fail, that doesn't mean that Tumor D isn't in the category of "responsive to the inhibition of $p34^{cdc2}$/cyclin B^{cdc13} kinase". Thus, how many different inhibitors (Y, Z, etc) must be tried before one concludes that Tumor D doesn't fall within the claim?

D. Conversely, if D does respond to Y but not to X, can one really conclude that D falls within the claim? It may be that the X result of failure is giving the accurate answer, and that the success of Y arises from some additional unknown property which Y is capable of. In other words, failure with X but success with Y does not answer the question of whether this tumor falls into the category of "responsive to the inhibition of

$p34^{cdc2}$/cyclin B^{cdc13} kinase." Thus, when mixed results are obtained, how many more pharmaceuticals need be tested?

E. Finally, suppose that X really will work, but only when combined with Z. There are for example, agents in anticancer technology which are not themselves effective, but the tumor will respond when the agents are combined with something else. Such does occur in the cancer area. How many adjuvants must be tried along with X to make sure that X really doesn't work? Presumably, if the tumor will respond to X when X is combined with adjuvant A, then the tumor is in the category of "responsive to the inhibition of $p34^{cdc2}$/cyclin B^{cdc13} kinase", so long as the tumor is not responding wholly to A.

F. In addition, it is unclear what level of response is meant by the "responsive" by the claim. For example, if the inhibitor causes the tumor to expand at only 95% of its previous speed, would that qualify? Keeping in mind that such a "response" would normally be considered as a failure in terms of therapeutic effectiveness, i.e. that the compound isn't effective, would that qualify as "responsive"?.

As a result, at present, determining the true scope of the claim will involve extensive and potentially open-ended oncological research. Without it, one skilled in the art cannot determine the actual scope of the claim. Hence, the claim is indefinite.

(11) Response to Argument

Appellants point to the presence of an essay on page 17-18. This response is inadequate. The specification does indeed provide an essay to determine if any given compound inhibits this kinase. But that is not the problem. All these compounds are already presumed to inhibit the kinase. If the claims were "a method of inhibiting

$p34^{cdc2}$/cyclin B^{cdc13} kinase" there would be no problem at all. The sole guidance that the specification provides is a mention of testing with bladder cancer, mentioned on page 19. The first test is with cells (*in vitro*), which is not a tumor test at all, since *in vitro* cells are not tumors. The second test is a tumor test, although, the specification provides no way of knowing what compounds, if any, were actually given either test. Even then, as set forth above, this is only the barest start toward answering the question of what is and is not included in the term "responsive to the inhibition of $p34^{cdc2}$/cyclin B^{cdc13} kinase". For example, if there were no response, that wouldn't prove that the tumor isn't on the list, because it could be that the particular compound chosen wasn't potent enough.

Appellants repeatedly refer to enablement on page 6 of the Appeal Brief. This is not an enablement rejection. The examiner does not allege lack of enablement, only that a phrase is indefinite. Likewise, Appellants cite *Skuballa* on the issue of "effective amount", but again, the rejection is not directed to the "effective amount" language at all.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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